ÖGSV Austrian Society for Sterile Supplies

A-8045 Graz, Ursprungweg 160
Tel: +43 (0) 316/69 47 11, Fax: Ext. 4
Email: office@oegsv.com
Internet: www.oegsv.com

ANNEX 2

to

Guideline

for Testing, Validation and Monitoring of Automated Cleaning and Disinfection Processes for Medical Devices

in compliance with
EN ISO 15883 Parts 1 and 2

Status: April 2005

Please send any suggestions for improving this Guideline or your experiences of implementing it to the following email address:

OEGSV
Email: office@oegsv.com

Table of Contents

Part A: Commissioning operational and organisational requirements

1 General information

Date or number of order:	
Date of test:	
Name and address of operator:	
Highest risk class of MDs to be reprocessed	☐ semi-critical A ☐ semi-critical B ☐ critical A ☐ critical B ☐ critical C
To be assigned accordingly to CSSD category, as per Article 94 of MPG Regulation	☐ I ☐ II ☐ IIIa ☐ IIIb
Responsible for reprocessing:	
Reason for test:	☐ - initial commissioning
	☐ - initial validation
	☐ - important changes made to process parameters
	☐ - expiry of test period (revalidation)
Type of test:	☐ - commissioning
	☐ - performance qualification
	☐ - recommissioning
	☐ - performance requalification
Name and address of test centre:	
Name of test engineer:	
Date of last test:	

2 Organisational preconditions for validation

2.1 Structural/spatial situation

	Yes	No	Remarks
Dedicated premises available			CSSD II, III
Separate unclean/ clean / sterile zones			CSSD II
Structural separation of unclean/ clean / sterile zones			CSSD III (new building)
Only structural separation of unclean +			Required for CSSD III (also old building)

clean / sterile zones			
Unclean/ clean sluice			CSSD III (new building: at least gown sluice)
Clean/ sterile sluice			CSSD III (if adjacent to OR)
Unclean area: surface provision enough			CSSD II,III
Clean area: surface provision enough			CSSD II,III
Separate changing rooms for clean/unclean area			
Structural defects			

Remarks on structural /spatial situation

2.2 Fittings

	Yes	**No**	**Remarks**
Washbasin in unclean area?			
- appropriate fittings?			
Ultrasonic basin available?			
- routine inspection?			type:
WDs available?			as from semi-critical B MDs
- WDs' capacity adequate?			
Rotary sealing machine?			as from critical A MDs
- routine inspection?			type:
Sterilizers available			as from critical A MDs
- steam sterilizer(s)			number: ☐ as per EN285
- formaldehyde (FO) sterilizers?			number:
- other:			
Remarks on fittings:			

2.3 Organisation

	Yes	**No**	Remarks
Is an up-to-date organigramme available? (enclose copy)			CSSD III
Are there written rules on responsibilities and competences?			CSSD II,III
Is release competence regulated?			
Is special release competence regulated?			
Is the presence of an on-site supervisor always assured (manager or deputy manager)			on-call service
Does the department reprocess MDs for external institutions?			
- to which category is this CSSD assigned?			
- to which RKI risk group do the MDs belong?			
- Are there contracts in place?			
- do they take account of the provisions of Article 94 of MPG Regulation?			
Remarks on organisation:			

2.4 Staff qualifications/ training

	Yes	**No**	Remarks
Management:	name:		
Nursing degree			as from CSSD II
Special training			which:
Specialist Course 1			
Specialist Course 2			as from CSSD II
Specialist Course 3			As from CSSD III
Specialist Course curriculum completed (examination)			As from CSSD III
At least 1-year's experience in MD reprocessing			
Since when have management duties been taken on?			

	Yes	No	Remarks
Deputy management:	name:		
Nursing degree			as from CSSD II
Special training			which:
Specialist Course 1			
Specialist Course 2			as from CSSD II
Specialist Course 3			as from CSSD III
Specialist Course curriculum completed (examination)			as from CSSD III
At least 1-year's experience in MD reprocessing			
Since when have management duties been taken on?			
Staff			
Number of additional staff			
Of whom with Specialist Course 1			

Training

	Yes	No	Remarks
Is there a training curriculum ?			CSSD III
- is this up to date?			
Has the scope of training been defined for new staff members?			CSSD II, III
- infection control (hygiene) training?			
- personnel protection training ?			
- equipment training?			
- is there evidence of training for new staff members?			
Is an internal audit of training conducted?			
How is the level of currently stipulated knowledge assured?			
Are spot checks conducted to assess staff members' level of knowledge:			
Remarks on qualifications /training:			

2.5 General infection control (hygiene)

	Yes	**No**	Remarks
Infection control policy (file) available?			
Cleaning and disinfection policy available?			
- is this up to date?			
- are the products available?			
- listed (tested) products?			
- instructions on personal hygiene?			
- instructions on hand hygiene?			
- instructions on changing rooms / sluices?			CSSD II,III
Remarks on general hygiene:			

2.6 Personnel protection

	Yes	**No**	Remarks
Is hepatitis B vaccination offered?			
Are there safety data sheets available on the chemicals used?			
Are there leaflets available on the action to be taken in the event of incidents involving biol. substances?			
Is there a system for reporting incidents involving biol. substances?			
Are near incidents recorded?			
Is personal protective equipment available?			
- gloves			
- gown			
- apron			
- orofacial mask			
- goggles			
- are sufficient quantities of these provided?			
- is the personal protective equipment			

used properly?			
Is training in personal protection provided annually?			
Remarks on personal protective equipment:			

3 Quality assurance/ management

3.1 General information

	Yes	**No**	**Remarks**
Are the MDs assigned to different risk categories as per Article 94 of MPG Regulation?			
Are the manufacturer's reprocessing instructions available?			to the extent they can be produced
Is amenability to reprocessing taken into account at the time of purchasing MDs?			
- are there written regulations for this?			
Are there regulations for:			
- compiling documents			CSSD III
- inspection of documents			CSSD III
- release of documents			CSSD III
Are test reports available on previous tests?			
- WDs			
- steam sterilizer(s)			CSSD III
- FO/EO (ethylene oxide) sterilizer(s)			CSSD III
Is a servicing schedule available?			CSSD II, III
- WDs			
- sterilizer(s)			
- ultrasonic basin			
- sealing machine			
- steam generator			
- osmosis system			

3.2 Washer-disinfectors

	Yes	No	Remarks
Is there a routine inspection schedule?			
Are routine inspections carried out?			
- of patency (endoscopes, MIS, etc.)			If applicable
- of cleaning			☐ visual inspection ☐ cleaning indicator, e.g. TOSI ☐ protein detection (e.g. Biuret)
- of disinfection			☐ regular thermometric tests ☐ visual temp. regulation ☐ indicator
- evidence of compliance with the disinfection cycle specifications			CSSD II, III
- Dosing process chemicals			
- inspection of cleaning arms when loading and unloading			If this can be done
Is provision made for batch documentation?			CSSD II, III
- sufficiently comprehensive and continuous?			

3.3 Sterilizers

	Yes	**No**	Remarks
Is there a routine inspection schedule?			CSSD II, III
Are routine inspections carried out?			
- vacuum test (at least weekly)			
- steam penetration test (Bowie & Dick test or equivalent test) – daily			
- evidence of compliance with the sterilisation cycle specifications			
- regular thermometric testing of a specific load (revalidation)			
Is provision made for batch documentation?			
- batch control system (PCD)			
- sufficiently comprehensive and continuous?			

3.4 Standard operating procedures

	Yes	**No**	Remarks
Are there standard operating procedures for:	CSSD II, III		
Collection / management of used MDs			
- how collected /managed?			
- has max. time used MDs left to dry been defined?			hours
Pretreatment			
Transport of contaminated MDs			
Receipt in the CSSD (incoming inspection)			
Dismantling instructions			
Manual precleaning			
Ultrasonic cleaning			
Washer-disinfectors			
- instructions for loading WDs			
- programme selection			
- control			
- release criteria			
- action taken for non-conformity with release criteria			
- action taken for malfunctions			
- action taken for errors			
Functional testing			
Care			
Packaging			
Sterilizer(s))			
- instructions for loading sterilizer(s)			
- programme selection			
- control			
- release criteria			
- action taken for non-conformity with release criteria			
- action taken for malfunctions			
- action taken for errors			
Transport of sterile MDs			
Storage			
- max. storage periods defined			
Application			
Handling special items			

3.5 Documentation

	Yes	No	Remarks
Is the following documentation available?			
Surface disinfection			
WD routine inspections			
WD batch documentation			CSSD II, III
Sterilisation routine inspections			
Sterilisation batch documentation			
- parametric release based on sample curves			CSSD III
Faults			
Mistakes / near mistakes			
Internal servicing			
External servicing (service engineer)			
- where is the documentation kept?			
Internal inspections/ tests (e.g. internal audits, assessment of training requirements)			
External inspections/ tests (e.g. Technical Inspectorate, validation, external audit, sanitary inspection)			
Feedback from clients or third parties			
Remarks on QM:			

Place / Date: /

Name:

Signature

Part B: Test Report

Test Report
No.:

on validation of cleaning and disinfection processes
for
surgical instruments
and
anaesthesia accessories

in washer-disinfector

Model:
Serial No.:

for

Site:

on

Contract awarder

As requested, the washer-disinfector designated below was tested as per prEN 15883 – 1 and 2. At the same time, validation of the cleaning and disinfection process was conducted in accordance with the "Guideline for testing, validation and monitoring of automated cleaning and disinfection processes for medical devices" of the Austrian Society for Sterile Supplies.

1 General information

Contract awarder:	
Address:	
Test site/ operator:	
Address:	
Responsible:	
Date of test:	
Test engineer:	
Reason for test:	
Date of last test:	

2 Commissioning washer-disinfectors

2.1 Information on WD tested

Designation of WD in institution		Inventory No.:	
Site:			
WD make:	WD for ☐ surg. instruments ☐ MIS instruments ☐ AN accessories ☐ containers ☐ flex. endoscopes ☐ other MDs: _____		
☐ Underbench WD	☐ Double-door WD		☐ Tunnel washer
☐ Serial device	☐ Custom-made	☐ Prototype	☐
Manufactured after EN 15883 came into force?		☐ yes	☐ no
Manufacturer:		Serial No.:	
Make:		Year of manufacture:	
Supplier:			
Last serviced:		Meter reading:	

n.e.: not evaluable, n.c. not conducted, n.a. not applicable

2.2 Technical requirements

Type test	**Yes**	**No**	**Remarks**
Is a certificate available on type test as per prEN 15883?			
Was the cleaning performance verified during the type test as per Annex B of EN 15883?			test soil: _____
Does the type test specify conditions?			
- if yes, have these been implemented?			
- was a repeat test conducted after elimination of defects			
- is there a report available on the repeat test?			
Remarks on the type test:			

The minimum requirements for washer-disinfectors manufactured before EN 15883 came into force are highlighted in grey; for washer-disinfectors that comply with EN 15883 the requirements are “MANDATORY”

Minimum technical requirements	Yes	No	Remarks
Door locked during process			
Mutual door locking mechanism in double-door machines			
Final rinse water disinfected			(for chemoth. disinf.)
- 60 °C continuously in tank			
- during disinfection phase (mind. 60 °C/3 min)			
Batch printer / recorder available?			
- only for disinfection phase			Minimum requirement for WDs used for (semi-) critical A MDs
- for cleaning and disinfection phase			Minimum requirement for WDs used for (semi-) critical (semi-) critical B or C MDs
- actual values recorded?			
Temperature displayed during programme cycle?			
- can temperature display be regulated?			
Batch counter available?			
Cycle stage display available?			
Water quantity used for each process step defined?			
- flow meter for incoming water supply?			
Dosing quantities defined for process chemicals?			
- cleaning			
- disinfection			
- neutralisation			
- rinse aid			
Dosing systems available?			
Dosing quantities verifiable volumetrically?			
Self-disinfection cycle available? *			
Cleaning arms unimpeded and smooth movement?			
Can be dismantled for cleaning?			
Servicing intervals displayed?			
Fault display?			
Test connection available?			
Remarks on technical requirements: * Required in tunnel washers for cleaning chamber(s), in single-chamber machines if only chemothermal programmes installed			

Accessories	Yes	No	Remarks
Loading rack for surg. instruments*	*		
Loading rack for MIS instruments*	*		
Loading rack for anaesthesia (AN) accessories*	*		
Loading rack for containers*	*		
- WD / loading rack docking OK?			
Loading rack suitable for instruments on site?			
Instrument trays amenable to cleaning?			
Remarks on WD accessories:			

* if such a programme is available

WD manufacturer's documentation	Yes	No	Remarks
Operating instructions available?			
Description of programme cycles available?			
- up to date?			
Evidence of instrument calibration (temperature sensors) available?			
Servicing manual available?			
Remarks on washer-disinfector documentation:			

"Yes" fields highlighted in grey are MANDATORY

2.3 Programme sequence of programmes tested (manufacturer's specification)

☐ A description of the programmes is given in the Annex

☐ Programme specifications were not available

	Programme		**Programme**		**Programme**		**Programme**	
Process	thermal		Thermal		thermal		thermal	
Phase	**°C**	**min**	**°C**	**min**	**°C**	**min**	**°C**	**min**
Prerinse 1								
Prerinse 2								
Cleaning 1								
Cleaning 2								
Neutralization								
Rinse 1								
Rinse 2								
Disinfection								
Drying								

2.4 Detergents and disinfectants used

	Name	**Programme**	**Dosage**
Detergent 1			
Detergent 2			
Disinfectant			
Neutralizing agent			
Rinse aid			

n.d.: no data

3 Information on testing

3.1 Scope of test/test methodology

Testing was conducted in accordance with prEN 15883-1 and 2 or with the ÖGSV Guideline for testing, validation and monitoring of automated cleaning and disinfection processes for medical devices.

Programme	Nature of test	Conducted
	Verification of disinfectant action (thermoelectric)	☐
	Verification of temperature course	☐
	Check of temperature display	☐
	Verification of cleaning performance	☐
	Verification of disinfectant action (microbiological)	☐
	Verification of dosing precision	☐
	Performance qualification	☐
	Operating media (softened, demineralised water)	☐
	Microbiological testing of final rinse water	☐

3.2 Thermoelectrical measurements

	Manufacturer/make	Serial No.:
Measuring equipment		
Temperature sensors		

Colour coding of recorder channels:

TE 1		TE 4	
TE 2		TE 5	
TE 3		TE 6	

4 Results

4.1 Technical defects

☐ No technical defects were detected.

☐ The following technical defects were detected:

4.2 Verification of disinfectant action (thermal programmes)

4.2.1 Chamber and loading rack

☐ conducted ☐ not conducted

4.2.1.1 Position of thermoelements (TE)

Programme 11	
TE 1	Tank
TE 2	Chamber wall, middle left
TE 3	Chamber wall, middle right
TE 4	Doors (loading side/ unloading side)
TE 5	Loading rack, top level left back
TE 6	Loading rack, bottom level right front

4.2.1.2 Results

Programme	$A_{0\ spec}$	Temp/Time $_{spec}$ [°C/min]	EWZ über °C [min]

☐ ***Measured value protocol is given in Annex***

4.2.2 Load

4.2.2.1 Position of thermoelements

Programme (Measurement 1)		Programme (Measurement 2)		Programme (Measurement 3)	
TE 1	Tank	TE 1	Tank	TE 1	Tank
TE 2		TE 2		TE 2	
TE 3		TE 3		TE 3	
TE 4		TE 4		TE 4	
TE 5		TE 5		TE 5	
TE 6		TE 6		TE 6	

4.2.2.2 Results

Programme	$A_{0\ spec}$	Temp/Time $_{spec}$ [°C/min]	EWZ über 90°C [min]

☐ ***Measured value protocol is given in Annex***

4.3 Check of temperature-controlled phases

☐ ***Measured value protocol is given in Annex***

4.4 Check of temperature display

Temperature display available: ☐ yes
☐ no

Recorder (batch printer) available: ☐ yes* ☐ no

Process step	Temp $_{spec}$ [°C]	Temp. display [°C]	Temp. batch printer [°C]	Temp. $_{meas.}$ [°C]	Deviation [K]

4.5 Verification of cleaning performance

4.5.1 Summary of results of tests with test soil

	Programme				
Process challenge device (PCD)	Chamber walls-loading rack	Scissors, clamps	Transport containers	MIS dummies	AN accessories
Test soil	KMNE*	hep. sheep blood	KMNE	hep. sheep blood	MNE**
Drying time	10 min	60 min	60 min	60 min	60 min
Number of soiled objects					
Number of objects with residual contamination					
Contamination rate %					
Requirement met:					

☐ see enclosed evaluation protocols

*German acronym for potato starch, flour paste, nigrosin, egg **German acronym for flour paste, nigrosin, egg

4.5.2 Summary of tests with cleaning indicators

	Programme	
Level reached in worst case		

☐ see enclosed evaluation protocols

4.5.3 Summary of protein detection test results

	Programme
Residual protein detected on supplies: level reached in worst case	

☐ see enclosed evaluation protocols

4.6 Performance qualification

4.6.1 Configurations tested

Config. No.	Programme	Loading trolley	Load
1		Instruments	
2		Instruments	
3		MIS	
4		Anaesthesia	
5		Containers	

4.6.2 Summary of results of cycles with instruments harbouring everyday soils

Config. No.	Number of MDs with residual contamination		Requirement met
	Visual inspection	Residual protein > 20 µg	
1			
2			
3			
4			
5			

☐ see enclosed evaluation protocols

4.6.3 Summary of protein detection test results

	Before cleaning	Programme		
		Test 1	Test 2	Test 3
Residual protein detected on supplies: level reached in worst case				

☐ see enclosed evaluation protocols

4.7 Dosing precision

☐ conducted ☐ not conducted

4.7.1 Programme

Process step	Product	Volume/cycle spec [ml]	Chemicals' volume/cycle meas. [ml]			Deviation %		
			Test1	Test2	Test3	Test1	Test2	Test3

spec: specified; meas: measured

4.8 Check of operating media

4.8.1 Chemical/physical investigation of water types used (incoming water supply)

☐ conducted ☐ not conducted

Sample	Needed for phases	PH	Total hardness [mmol Ca CO_3/L]	Conductivity [µS/cm]	Turbidity
Softened water				-	
Demineralised water					

4.8.2 Microbiological testing of final rinse water (incoming demineralised water supply)

☐ see enclosed results ☐ not conducted

4.9 Residues in final rinse water

4.9.1 Chemical investigation of final rinse water (chamber)

☐ conducted ☐ not conducted

	PH	Total hardness [mmol Ca CO_3/L]	Conductivity [µS/cm]	Turbidity	Silicium [mg/L]	Residual chlor. [mg/L]
Final rinse water						

4.9.2 Microbiological testing of final rinse water (chamber)

☐ see enclosed results ☐ not conducted

5 Acceptance criteria

5.1 Disinfectant action (thermal programmes)

The specified Ao value must be achieved.

5.2 Disinfectant action (chemothermal programmes)

In the disinfection phase the microbial count must be reduced by 5 log levels.

5.3 Temperature course

The temperature course is evaluated as per Annex 1 of the ÖGSV Guideline for testing, validation and monitoring of automated cleaning and disinfection processes for medical devices.

5.4 Temperature display

Max. deviation: ± 2 °C of reference value.

5.5 Cleaning performance

5.5.1 Operational qualification

Evaluation is conducted on completion of the cleaning phase:

The cleaning process is deemed satisfactory for standard surgical instruments if:

- *At least 95 % of PCDs are free of residual contamination;*
- *The indicators, if used, show results that are within the range of acceptance criteria specified by the manufacturer (if TOSI PCDs are used, levels 0 and 1 can be tolerated);*
- *The residual protein content is < 20 µg/ PCD or within the range of acceptance criteria specified by the manufacturer, if applicable.*

The cleaning process is deemed satisfactory for MIS surgical instruments if:

- *None of the PCDs harbour any visible residual contamination;*
- *The residual protein content is < 100 µg/ PCD or within the range of acceptance criteria specified by the manufacturer.*
- *The indicators, if used, show results that are within the range of acceptance criteria specified by the manufacturer*

The cleaning process is deemed satisfactory for instruments contaminated with MNE soils if:

- *None of the PCDs harbour any visible residual contamination;.*
- *The residual protein content is below the detection limit*

5.5.2 Performance qualification

Evaluation is conducted at the end of the programme (cleaning and disinfection).

The cleaning performance is deemed adequate if:

a) There is no visible residual contamination.

b) A residual protein content of 20 µg/ instrument is not exceeded (Protect M: level x)

5.6 Operating media

	pH	Total hardness [mmol Ca CO_3/L]	Conductivity [µS/cm]	Turbidity
Softened water	6-8	As per manufacturer's instructions	-	Clear, colourless, without any precipitates
Demineralised water	6-8	≤ 0.2 mmol/l	≤ 15µS/ cm	Clear, colourless, without any precipitates

5.7 Residues in the final rinse water (chamber)

Bacteriological: colony forming units (cfu) (36±2 °C/ 48±4 h): 100, *Pseudomonas aeruginosa* n.n. in 100 ml.

Chemical:

	pH	Total hardness [mmol Ca CO_3/L]	Conductivity [µS/cm]	Turbidity	Silicium [mg/L]	Residual chlor. [mg/L]
Final rinse water	6-8	≤ 0.1 mmol/l	*	Clear, colourless, without any precipitates	≤1	≤ 0.1

* not yet defined

5.8 Dosing precision

Max. deviation from setpoint value or reproducibility: ± 10 %

6 Evaluation

6.1 Operational qualification

The requirements were met for:	**Programme**		
Cleaning performance			
Disinfectant action			
Temperature course			
Dosing precision			

The requirements were met for accuracy of temperature display	☐ yes	☐ no	☐ n.a.
The requirements for the operating media were met	☐ yes	☐ no	☐ n.c.
The requirements for the final rinse water were met	☐ yes	☐ no	☐ n.c.

n. c.: not conducted; n.a. : not available; s.O: see remarks for operator

6.2 Performance qualification

The requirements were met for:	**Programme**		
Cleaning performance for instruments harbouring everyday soils			

7 Remarks for the operator

- Cleaning performance:
- Disinfectant action:
- Temperature course
- Dosing precision
- Temperature display
- Operating media
- Final rinse water
- Performance qualification

8 Summary of evaluation

Next inspection recommended: /

Further remarks: The test results refer exclusively to the machine tested. Without the permission of the test institute, the test report may be reproduced only in its entirety.

Signature of person responsible for test:

Place / date: / Name:

Signature

Signature of person responsible for evaluation and compilation of report:

Place / date: / Name:

Signature

Signature of person responsible for acceptance of report in the respective institution

Place / date: , / Name:

Signature

☐ Measured values recorded for test disinfection cycles
☐ Programme specifications
☐ Annex: Cleaning performance and TOSI evaluation tables
☐ Annex: Performance qualification

Annex 1:

Evaluation of cleaning performance with test soil (example)

WD		**Operator**			**Date:**		
Prog.		**Batch No.:**			**Load:**	**Instruments**	
Level	**Supplies**	**Test soil**	**Number of items**	**Optically clean**	**Not clean**	**Contamination rate (%)**	**Biuret reaction (degree)**
	Clamps / scissors	Blood	20			0	
	Clamps / scissors	Blood	20			0	
	Clamps / scissors	Blood	20			0	
			120	0	0	**0.0**	

Programme settings:
Prerinse:.....min
Prerinse:.....min
Dose at .....°C/ .....(....ml)
Cleaning:..... °C.....min
Neutralization:.....min
Intermediate rinse:.....min

Verification of cleaning with process challenge devices

Programme:					**Operator:**
Load: instruments					**Date:**
Schema as per drawing:					
Test:	**Level**		**Position as per drawing**	**Result (level)**	**Drawing**

Annex 2:

Evaluation of performance qualification

Configuration No.:

Date:	
Programme:	
Load:	
Batch number:	
Drying time:	
Tested by:	
Evaluated by:	
Programme start (time):	
TOSI:	☐ conducted ☐ not conducted
Assessment of drying:	☐ conducted ☐ not conducted

Visual inspection: MDs with residual contamination	
Number	**Designation of MD**

Determination of residual proteins on selected MDs	
Designation of MD	**Results of residual protein content in µg (referred to protein standard)**

Verification of drying: MDs with residual moisture	
Designation of MD	**Result**